



# INTERIM REPORT FIRST QUARTER 2021

Xspray Pharma is a product development company that focuses on cost-efficient development of improved and generic versions of orphan drugs with high value, primarily protein kinase inhibitors (PKIs). The improved versions are formulated as hybrid nanoparticles (HyNap's) and are patentable, stable and 100 percent amorphous solid dispersions of crystalline original substances.

## Significant events during the first quarter

### January - March 2021

- In January, Xspray Pharma announced the results of an extra bioequivalence (BE) study on fed and fasting healthy volunteers that was conducted with the company's leading product candidate, HyNap-Dasa. The results are in line with previous bioequivalence studies in which formal bioequivalence was not achieved in the fasting group. The study was conducted with formulation A, the same formulation used in earlier BE studies in 2020.
- In January, BE studies were initiated with a new version of HyNap-Dasa – HyNap-Dasa formulation B, a slightly altered formulation.
- In January, Xspray Pharma announced that CEO Per Andersson and other warrant holders had chosen to fully utilize the option to subscribe for shares in Xspray Pharma through their respective exercise of the number of warrants in the LTIP 2015/2021 warrant program. As a result, the number of shares outstanding and votes increased by 175,000 and thereby total 19,067,504. The share capital increased by SEK 175,000 from SEK 18,892,504 to SEK 19,067,504.
- In February, Xspray Pharma announced that the Nomination Committee had proposed Anders Ekblom for election as the new Chairman of the Board of Xspray Pharma at the coming Annual General Meeting on May 20, 2021. The Committee further proposed the re-election of Board members Gunnar Gårdemyr, Maris Hartmanis, Torbjörn Koivisto, Christine Lind and Carl-Johan Spak as well as the election of new Board members Anders Ekblom and Anders Bladh. Anders Bladh is the CEO and a Board member of Ribbskottet AB, which is the second largest owner of Xspray Pharma.
- In March, Xspray Pharma announced that all the healthy volunteers in the bioequivalence studies with a modified tablet formulation of the generic HyNap-Dasa ANDA, formulation B, had been given the complete dosage. The studies were conducted in two groups of healthy volunteers under fed and fasting conditions.

- In March, Xspray Pharma provided an update of the planned registrational studies with the improved version of Sprycel® (dasatinib), based on the company's HyNap-Dasa formulation. The work on the study has commenced, and the dosing for the bioequivalence study will begin in the second quarter.

### Significant events after the end of the reporting period

- In April, Xspray Pharma announced the results of two bioequivalence studies in fed and fasting healthy volunteers with a slightly modified tablet formulation of the generic product candidate HyNap-Dasa, formulation B. Bioequivalence with Sprycel® was achieved in the study in fed condition. The study in fasting condition demonstrated a lowered level of absorption of HyNap-Dasa, but the effect was not sufficient to achieve bioequivalence.
- In April, Xspray Pharma announced that the company's improved version of Sprycel® (dasatinib), HyNap-Dasa 505(b)(2), was expected to have a significantly improved product profile with more efficient absorption, which would lead to medically relevant advantages for patients. This version is based on the thoroughly tested formulation A, and will be tested in a registrational bioequivalence study in the second quarter.
- In April, Xspray Pharma released the notice to attend the Annual General Meeting on Thursday, May 20, 2021. In light of the COVID-19 pandemic, the meeting will be conducted solely through advanced voting by virtue of temporary legislation.

#### January - March 2021, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -13,912 thousand (-10,532)
- Earnings per share before dilution amounted to SEK -0.73 (-0.63)
- Cash flow from operating activities amounted to SEK -11,971 thousand (-13,490)
- Cash flow from investing activities amounted to SEK -25,188 thousand (-23,918)

*Amounts in brackets refer to the year-earlier period.*



## A message from the CEO

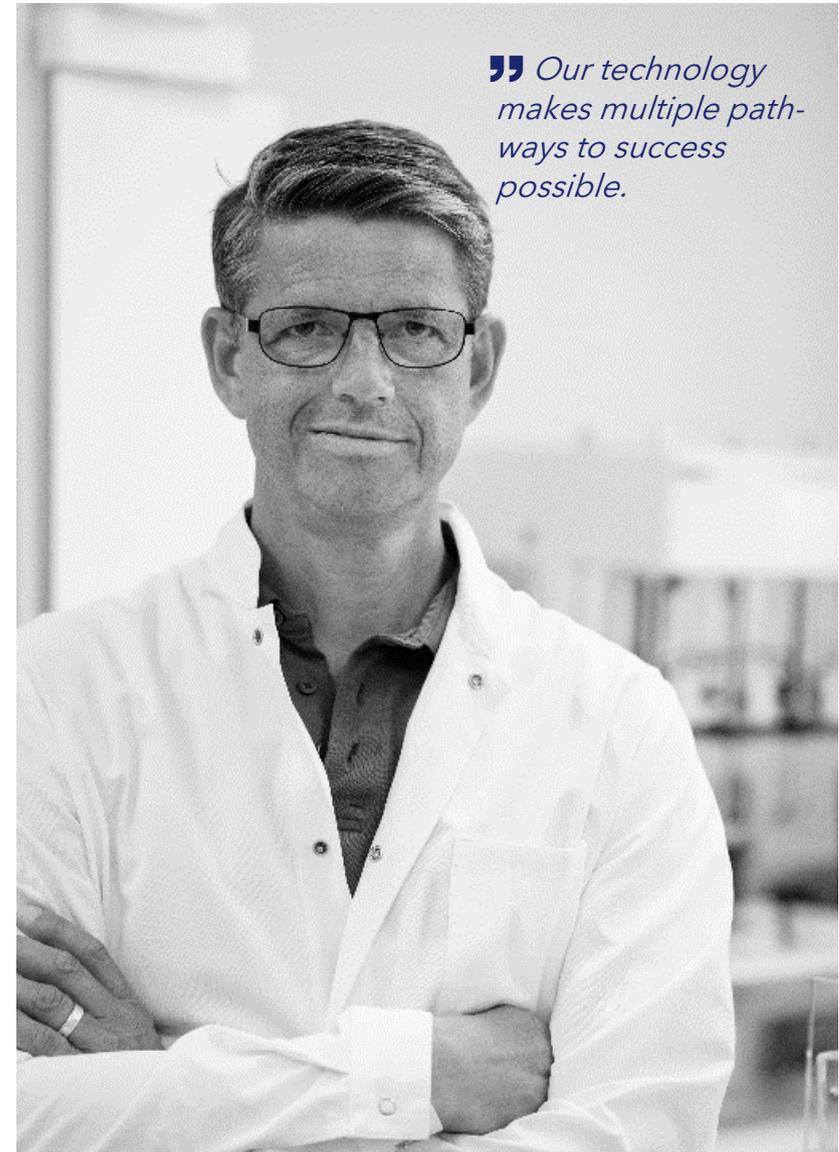
# Multiple pathways to success

We are working on a technology platform with potential for many PKI products. The results of the latest studies have set us back, but in a greater perspective it is an unwelcome but minor obstacle. What makes the product platform possible is the unique technology behind the HyNap formulations that can be scaled up. This is the single most important factor for Xspray Pharma over the long term. Previously, I said that it was not a question of if a HyNap-Dasa product could be released, but when. This is still the case, and as this year continues, I am convinced that we will demonstrate positive results from the study and submit an application for market approval.

Alongside the work on HyNap-Dasa, we are now preparing our next product candidate, HyNap-Nilo, for the pilot study that precedes a future bioequivalence study. Tests and evaluations are under way to determine which PKIs will become new HyNap projects and be included in our pipeline. I can state that the development of our first product candidate, HyNap-Dasa, will be the first example of how our technology platform will make multiple pathways to success possible. The development of the product line in Malta will mean an increase in production capacity of drug candidates that can meet market demand for PKI drugs.

In the first quarter, we received the results from the study of HyNap-Dasa formulation B, which was a slightly modified version of the previously tested formulation A. Bioequivalence with Sprycel® was achieved in the study in fed subjects, but not in the study in fasting subjects. The high variability in the original product was the reason we did not achieve bioequivalence for fasting healthy volunteers.

It is obvious that we have developed a formulation that is significantly better than the formulation of the original tablet. The formulation B results showed that our tools for modifying the formulations work; we were close to the low levels of the original in fasting healthy



” *Our technology makes multiple pathways to success possible.*

subjects, but the modification was not enough to achieve bioequivalence. This strengthens my confidence in formulation C, which was developed to further decrease absorption, and I therefore look forward to the results from that study. A generic product will remain highly valuable, even with later market approval than estimated.

It is highly interesting and gratifying to be able to test our formulation A in a new bioequivalence study with Sprycel<sup>®</sup>, now as an improved formulation of dasatinib, where the advantages of the HyNap technology can provide relevant improvements for both doctors and patients. Formulation A in several studies has shown that it has approximately 30 percent higher uptake compared to Sprycel<sup>®</sup>, which is why we will now test a lower strength of HyNap-Dasa A against Sprycel<sup>®</sup>. In addition to being able to calculate what the results will be using existing data, there is a great deal of documentation in place for quick submission of an application for market approval under the 505(b)(2) procedure to the US Food and Drug Administration in the event of a positive outcome from the study.

It is estimated that an improved product will not be affected by the original company's secondary patent – which for Sprycel<sup>®</sup> expires in 2026 – but that doctors will be able to prescribe the product where they see a need for it. Our numbers show that up to 50 percent of patients with CML use omeprazole or other peptic ulcer medicine to raise pH levels in the stomach. This is something that is advised against in the current original product, since it drastically reduced the uptake of dasatinib. Through the studies, we have already demonstrated the beneficial profile of our product – meaning that it is not affected by food and medicines that raise pH levels, such as antacids or proton-pump inhibitors. In addition, the uptake with our product is less variable compared with Sprycel<sup>®</sup>, which results in a safer, more comfortable treatment.

As with all drugs, and especially important in cancer treatments, being in the “therapeutic window” – meaning the concentration of drugs in the body that is most effective against cancer – is desirable. Too low an uptake of the drug is not good, since the cancer can begin growing again, and too high a concentration is undesirable since it could result in side effects that are so difficult that treatment must be suspended or changed to another drug, if one exists. Here, our improved product will have a strong potential for capturing a solid market share by refining the treatment and thereby improving the quality of life for patients.

We look forward with confidence to an exciting continuation of 2021.

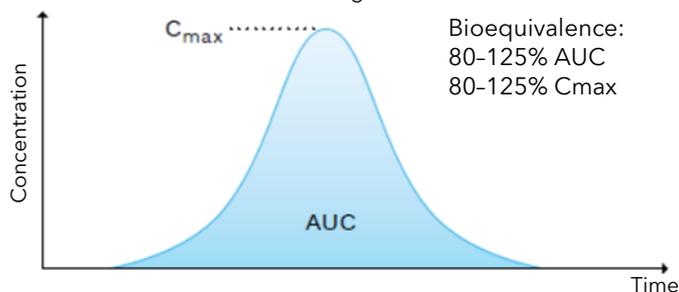
May 6, 2021

*Per Andersson*  
CEO

## Business focus and prospects

**Xsray Pharma AB (publ)** is a product development company with multiple product candidates in clinical development phase. Xsray Pharma uses its innovative, patented technology to develop fully amorphous product candidates that are improved and/or generic versions of marketed drugs, primarily protein kinase inhibitors (PKIs) for the treatment of cancer. Often the original companies have secondary patents that are based on the crystalline forms of the active substance. Due to the fact that Xsray Pharma's products are fully amorphous, they can be marketed as soon as the original companies' drug substance patents expire. This is a unique opportunity for market establishment several years ahead of generic products gaining access to the market.

In bioequivalence studies conducted in healthy volunteers, the goal is to achieve bioequivalence comparable to the reference drug, meaning that the active drug substance of the product candidate should be processed by the body the same way as the reference drug. Bioequivalence must be achieved regardless of whether the company develops improved or generic versions of the reference drug.



Bioequivalence is measured as the area under the curve (AUC) and as maximum blood plasma concentration ( $C_{max}$ ).

The company's initial product candidates – HyNap-Dasa, HyNap-Nilo and HyNap-Sora – are stable amorphous versions of the three best-selling cancer drugs Sprycel® (dasatinib), Tassigna® (nilotinib) and Nexavar® (sorafenib). In 2020, Sprycel® sold for USD 2.1 billion, Tassigna® for USD 1.96 billion and Nexavar® for USD 729 million. A careful selection process determines which PKIs will become future product candidates and be included in the company's pipeline once manufacturing capacity is possible.

### Market

PKI drugs are the second largest drug segment for targeted cancer therapies, where sales total approximately 25 percent of the total oncology market, and with sales figures that are increasing annually. In 2020, sales of PKI drugs in the US market totaled approximately USD 24 billion.

Demand for effective life-cycle products is increasing in pace with the expiration of patents for many crucial original drugs. Of the 55 PKIs currently being marketed in the US, 23 drug substance patents are expected to expire by 2030. To date, Xsray Pharma has tested its technology on some twenty of the PKIs established in the US market, with positive results.

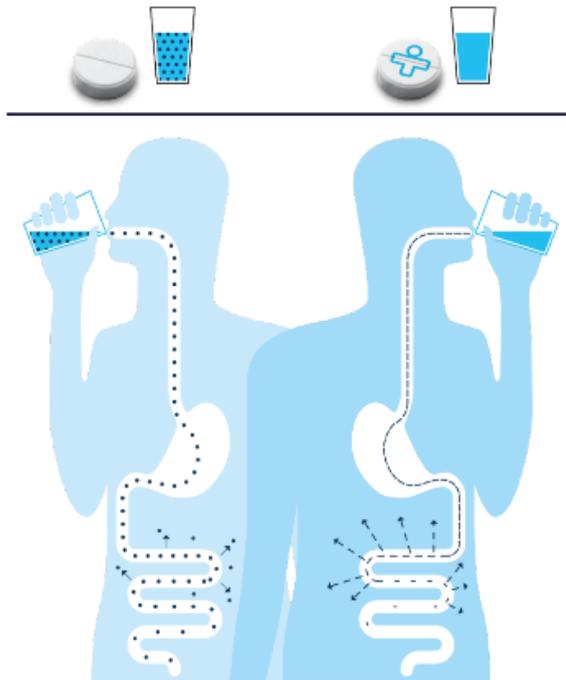
### PKI drugs with challenges

Protein kinase inhibitors (PKIs) have been shown to inhibit the growth of cancer, which results in extended survival and the patient most often being treated for several years – in some cases, for life. The majority of the PKIs being marketed contain crystalline forms of the active substances. One generally known problem with these products is that they are difficult to dissolve and depend on the pH value in the stomach for uptake in the body. This results in a highly uneven uptake of the drug into the body, especially alongside the ingestion of food or pH-increasing drugs such as omeprazole.

### Xspray Pharma has the solution

Xspray Pharma's technology is especially suited to overcoming the shortcomings that PKI substances generally possess. The company produces stable amorphous PKIs that can be easily dissolved and are pH-independent, which means a more even uptake of the drug even alongside the ingestion of food or pH-increasing drugs.

Moreover, this technology makes it possible to adjust how much of the drug is to be taken up into the body.



Xspray Pharma's amorphous products are easily dissolved and independent of the pH value in the stomach, which yields a more even uptake of the drug into the body in contrast to the crystalline products.

### Prospects

The company's new HyNap product candidates are being developed in the same manner as the company's initial product, HyNap-Dasa. The process is reproducible and reduces the effective development time for future products in the company's pipeline. Moreover, the technology makes it possible to quickly and in a controlled manner change the properties required to make either generic or improved versions of PKI drugs already being marketed and to bring the respective product candidates to market. This means the company has the conditions for meeting market demand.

Xspray Pharma's goal is to be a leader in developing improved and generic versions of PKIs already being marketed for the treatment of cancer. The company has patented the manufacturing technology, the equipment, and the resulting products.

## Xspray Pharma’s product portfolio

Xspray Pharma’s product portfolio is continuously evolving and, to date, has three product candidates based on the company’s HyNap platform: HyNap-Dasa, HyNap-Nilo and HyNap-Sora. All are generic or improved versions of established and marketed protein kinase inhibitors with orphan drug status. The original drugs have secondary patents expiring between 2026 and 2029 and their total annual sales for 2020 exceeded USD 2.3 billion in the US market and USD 4.8 billion globally.

### HyNap-Dasa as an improved and generic version

HyNap-Dasa is Xspray Pharma’s leading product candidate and is based on BMS’s Sprycel® (dasatinib) for the treatment of chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL). The primary patent for Sprycel® expired in December 2020 and the secondary patent expires in 2026, which could give HyNap-Dasa a period of several years with less competition before other competitors gain access to the market. In 2020, the global market for Sprycel® amounted to approximately USD 2.1 billion, of which the US market accounted for approximately USD 1.3 billion.

Product		Patent				Developing phase					
Project	Substance	Key indication	Regulatory process	Substance IP expiry-date	Secondary IP expiry date	New product development	Formulation development	Pilot studies	Pivotal studies	Regulatory review	Original-product/ Company
HyNap-Dasa	dasatinib	Leukemia (CML, ALL)	ANDA	Jan 2020	Sept 2026						Sprycel®/ BMS
HyNap-Dasa	dasatinib	Leukemia (CML, ALL)	505(b)(2)	Jan 2020	Sept 2026						Sprycel®/ BMS
HyNap-Nilo	nilotinib	Leukemia (CML)	505(b)(2)	Jan 2024	Feb 2029						Tasigna®/ Novartis
HyNap-Sora	sorafenib	Liver cancer (HCC)	505(b)(2)	Jan 2020	Dec 2027						Nexavar®/ Bayer
HyNap-New	not communicated										

#### Clinical studies with HyNap-Dasa for a generic version of Sprycel® (dasatinib), ANDA

In 2020, a registrational study was conducted as part of the requirements for submission of an ANDA application to the FDS for market approval of the generic version in the US, and in the second half of 2020, the results of two studies conducted in fed and fasting volunteers respectively were announced. Both studies were conducted with the primary goal of demonstrating bioequivalence with HyNap-Dasa and the reference product Sprycel®. Formulation A, the first formulation produced on a commercial scale, was used in these studies.

The study in fasting healthy volunteers did not meet the statistical requirements for bioequivalence, primarily because the reference drug Sprycel® showed low or no absorption in a small number of subjects. However, this was not observed for HyNap-Dasa. The second study, in fed conditions, achieved the objective of bioequivalence. The study with formulation A in fasting volunteers was repeated later that same year, but with the same negative results.

A new bioequivalence study with a new formulation B was begun in the first quarter of 2021, and the results from this was announced after the end of the first quarter. The modification of the formula was not sufficient, the results were lower but did not meet the requirements of bioequivalence. Bioequivalence was achieved in fed conditions, but not in the group with fasting subjects. The company is now planning for new bioequivalence studies with a more modified version of HyNap-Dasa: the "C" formulation, and these are scheduled to commence in the second quarter with preliminary results in the third quarter of 2021. This formulation will further reduce the absorption levels, which has been demonstrated in laboratory tests.

#### Clinical studies with HyNap-Dasa for an improved version of Sprycel® (dasatinib), 505(b)(2)

The company will initiate registrational studies with the improved version of dasatinib in the second quarter of 2021. This formulation is based on the thoroughly tested formulation A. External experienced pharmacokinetic experts have estimated, based on existing clinical data, that the product will be bioequivalent to Sprycel® with a 30 percent decrease in the dose.

Bioequivalence studies conducted in humans confirm that the formulation:

- can be used together with omeprazole without affecting the absorption of dasatinib, which facilitates a treatment of peptic ulcers while the patient is being treated for cancer
- yields a more even and consistent uptake of dasatinib without those cases of low uptake linked to previous studies with Sprycel®
- can be administered at a lower dosage, which is expected to yield fewer side effects

#### HyNap-Nilo

Xspray Pharma is developing HyNap-Nilo as an improved version of Tasisna® (nilotinib) for the treatment of chronic myeloid leukemia (CML). Global sales of Tasisna® totaled USD 1,958 million in 2020, of which the US market accounted for USD 859 million.

Tasisna's drug substance patent expires in January 2024, and the secondary patent in February 2029. Xspray Pharma has conducted a clinical trial that investigated the pharmacokinetic properties and food interaction of a HyNap-Nilo prototype. The study showed that HyNap-Nilo significantly reduces food interaction compared with Tasisna® after a high-fat meal. Clinical study results have indicated the bioavailability of HyNap-Nilo to be 2.4 times greater than Tasisna®. Like Xspray Pharma's other candidates, HyNap-Nilo also displayed lower variability compared with Tasisna®.

The US Food and Drug Administration has granted orphan drug status to HyNap-Nilo for the treatment of chronic myeloid leukemia (CML).

The development of the commercial formulation and manufacturing of clinical trial materials is progressing, and new clinical studies are planned in 2021.

#### HyNap-Sora

Xspray Pharma is developing HyNap-Sora as an improved version of Nexavar® (sorafenib) for the treatment of renal cancer, liver cancer as well as several forms of thyroid cancer. Global sales of Nexavar® in 2020 totaled USD 729 million, of which the US market accounted for USD 194 million. Nexavar's primary drug substance patent expired in January 2020, and the secondary patent in the US expires in December 2027.

A pharmacokinetic study in 14 healthy subjects was conducted with HyNap-Sora 100 mg against Nexavar® 200 mg. The study showed that the bioavailability of HyNap-Sora was nearly double the bioavailability of Nexavar®. The variability in both AUC and C<sub>max</sub> among subjects was also reduced by approximately half.

## Financial overview, Group

<b>Key figures group</b>	<b>Q1</b>		<b>Full year</b>
	<b>2021</b>	<b>2020</b>	<b>2020</b>
Net sales (SEK thousand)	-	-	-
Loss before Income tax (SEK thousand)	-13,912	-10,532	-52,410
Earnings per share before dilution (SEK)	-0.73	-0.63	-3.05
Earnings per share after dilution (SEK)	-0.73	-0.63	-3.05
Research and development expenses as % of operating expense	11.4	15.1	11.9
Cash and cash equivalents (SEK thousand)	292,265	172,740	325,598
Total assets (SEK thousand)	594,178	383,061	605,303
Equity/assets ratio (%)	96.4	94.9	96.2
Average number of employees	21	18	20

Total expenditures for research and development totalled SEK -27,095 thousand, of which SEK -1,626 thousand has been expensed and SEK -25,470 thousand capitalized as development expenditures.



## Comments on the report

Unless otherwise indicated, the comments below pertain to the Group. Comparison figures are presented in parentheses and pertain to the year-earlier period. Since the Group consists of the Parent Company and a dormant subsidiary, the differences between the Parent Company and consolidated statements consist of the differences between RFR2 and IFRS.

### Net sales

Net sales for the company remain at SEK 0. Market approval of the first product is planned in 2021.

### Other operating income and expenses

Other operating income for the period amounted to SEK 100 thousand (0). Other operating expenses for the period amounted to SEK -470 thousand (-540). Both categories consist entirely of exchange rate gains and losses arising in conjunction with payments abroad.

### Research and development costs

Total expenditures for research and development for the quarter amounted to SEK -27 095 thousand (-22 095), of which SEK -1,626 thousand (-1,621) has been expensed and thereby recognized in profit or loss, and SEK 25,470 thousand (20,474) has been capitalized as development expenditures and is presented in the company's balance sheet. The majority of the cost increase is attributable to higher clinical costs as well as increases in other activity in the company's two product candidates, HyNap-Dasa and HyNap-Nilo.

### Administrative and sales costs

Administrative and sales costs for the first quarter of 2021 amounted to SEK -12,182 thousand (-8,552); of these, personnel costs classified as administrative, and sales costs amounted to SEK -3,895 thousand (-3,163). The cost increase reflects continuing activities attributable to the company's research projects that have not been capitalized as well as consulting costs linked to the company's operating activities. The company's personnel has increased by three full-time positions compared with the year-earlier period, which impacts the cost base.

### Loss for the period

Loss for the quarter amounted to SEK -13,912 thousand (-10,532). This corresponds to earnings per share before dilution of SEK -0.73 (-0.63).

### Cash flow, investments, and financial position

Cash flow from operating activities for the quarter amounted to SEK -11,971 thousand (-13,490) of which the effect from operating capital comprised SEK -416 thousand (-4,352). The continued negative cash flow is in accordance with the company's plan, and is primarily attributable to a strengthened organization, increased project costs and other advisory services for the company's future strategic positioning

Cash flow from investing activities amounted to SEK -25,188 thousand (-23,918). The item consists solely of capitalized development expenses of SEK -25,188 thousand (-20,193). Investment in property, plant and equipment for the period amounted to 0 thousand (-3,725), the increase in the balance sheet is due to ongoing new construction of SEK 7,156 thousand being reclassified to machinery as a result of the completion of a machine production line. Cash flow from investing activities is in line with expected development and is forecast to increase as a result of the continued work on the company's new production unit.

Cash flow from financing activities for the quarter amounted to SEK 3,826 thousand (276), the positive effect derived from the redemption of warrants from the LTIP 2015/2021 program. In total, 175,000 warrants were redeemed at a value of SEK 4,375 thousand. Total cash flow for the first quarter was SEK -33,333 thousand (-37,132). The Group had SEK 292,265 thousand (172,740) in cash and cash equivalents at March 31, 2021.

Company operations are financed primarily by equity. The Board of Directors feels that the company's financial position over the next twelve-month period is good, with an acceptable and manageable level of risk in the product portfolio. The Board routinely evaluates the company's financial requirements and financial position and reviews the best capital structure for the company.

The debt/equity ratio for the Group was 96.4 per cent (94.9) at March 31, 2021.

#### Intangible fixed assets

Development expenditures for the projects have been capitalized according to plan. The Group's capitalized development expenditures for the quarter amounted to SEK 25,470 thousand (20,474). The Group's total capitalized expenditures for development and similar activities totaled SEK 257,088 thousand (161,989) at March 31, 2021. The item is associated primarily with the company's leading product candidate, HyNap-Dasa.

#### Parent Company

The Parent Company's subsidiary, Xspray Pharma Futurum AB, remained dormant during the period. All activities were pursued in the Parent Company, Xspray Pharma AB (publ). The Parent Company had SEK 292,215 thousand (172,690) in cash and cash equivalents at March 31, 2021.

#### Employees

The organization expanded by one full-time position in the quarter. The number of employees in the Group totaled 21 (18). The subsidiary had no employees as of the balance date.

#### Related-party transactions

The company's Chairman of the Board performs consultant assignments in business development and legal advisory services for the company. The associated costs for the quarter amounted to SEK 0 thousand (-91).

#### Corporate governance

The Audit and Remuneration Committees continued to assist the Board of Directors regarding monitoring assignments and remuneration issues.



## Share information

Xspray Pharma's share has been listed on Nasdaq Stockholm in the Mid-Cap segment under the symbol XSPRAY since March 27, 2020. Prior to that, the share was traded on Nasdaq First North Growth market beginning September 28, 2017.

During the quarter, the company's shares and votes increased as a result of warrants being exercised. The number of shares increased by 175,000. At March 31, 2021, the number of shares in the company was 19,067,504 and the last price paid in the period was SEK 107.00.

### Incentive plans

During the quarter in question, all warrant holders chose to exercise their option to subscribe for shares as a result of the expiration of the company's LTIP 2015/2021 incentive plan. The number of shares and votes thereby increased by 175,000.

At March 31, 2021 the company had two series of warrants issued to senior executives and employees. The remaining warrant programs are LTIP 2018/2022 and LTIP 2020/2023, which comprise a total of 292,996 warrants outstanding.

Refer to the Annual Report for 2020 for an account of the utilized and remaining incentive plans.

<b>Owners as of March 31, 2020</b>	<b>Number of shares</b>	<b>Number of shares &amp; votes</b>
Östersjöstiftelsen	2,500,826	13.12%
Ribbskottet AB	2,105,000	11.04%
Swedbank Robour Fonder	1,550,000	8.13%
Fjärde AP-Fonder	1,498,500	7.86%
TiN Fonder	835,590	4.38%
Avanza Pension	768,447	4.03%
Unionen	726,000	3.81%
Futur Pension	403,730	2.12%
Andra AP-fonden	394,738	2.07%
C WorldWide Asset Management	320,000	1.68%
<b>Total, ten largest owners</b>	<b>11,102,831</b>	<b>58.23%</b>
<b>Total, other shareholders</b>	<b>7,964,673</b>	<b>41.77%</b>
<b>Total number of shares</b>	<b>19,067,504</b>	<b>100.00%</b>

### Financial calendar

Annual General Meeting	May 20, 2021
Interim report Q2	August 6, 2021
Interim report Q3	November 4, 2021
Year-end report 2021	February 18, 2022

The financial reports will be made available on the Xspray Pharma website on the above reporting dates, [www.xspraypharma.com](http://www.xspraypharma.com).

### Analysis monitoring the company

Filip Einarsson, Redeye  
Naresh Chouhan, Intron Health

## Financial statements and notes

Xspray Pharma AB (publ) acquired a newly-formed subsidiary in December 2018, which remains dormant. No activity has taken place in the subsidiary; all activities are pursued in the Parent Company, Xspray Pharma AB (publ).

### Consolidated income statement

SEK thousand	Q1		Full year
	2021	2020	2020
Net sales	-	-	-
Other operating income	100	-	1,364
Research and development expenses	-1,626	-1,621	-6,549
Administration and sales expenses	-12,182	-8,552	-47,101
Other operating expenses	-470	-540	-1,171
<b>Operating loss</b>	<b>-14,177</b>	<b>-10,714</b>	<b>-53,457</b>
Finance income	266	186	1,053
Finance costs	-0	-4	-6
<b>Finance net</b>	<b>266</b>	<b>182</b>	<b>1,047</b>
<b>Loss before Income tax</b>	<b>-13,912</b>	<b>-10,532</b>	<b>-52,410</b>
Tax	-	-	-
<b>Loss for the period</b>	<b>-13,912</b>	<b>-10,532</b>	<b>-52,410</b>
Earnings per share for the period before dilution, SEK	-0.73	-0.63	-3.05
Earnings per share for the period after dilution, SEK	-0.73	-0.63	-3.05
Average number of shares before dilution	19,002,616	16,751,622	17,211,467
Average number of shares after dilution	19,081,690	17,206,213	17,679,463

### Consolidated statement of comprehensive income

SEK thousand	Q1		Full year
	2021	2020	2020
<b>Loss for the period</b>	<b>-13,912</b>	<b>-10,532</b>	<b>-52,410</b>
Other comprehensive income	-	-	-
<b>Total comprehensive income for the period</b>	<b>-13,912</b>	<b>-10,532</b>	<b>-52,410</b>

*Profit for the period and comprehensive income are attributable in their entirety to Parent Company shareholders.*

## Consolidated balance sheet

SEK thousand	31 Mar 2021	31 Mar 2020	31 Dec 2020
<b>ASSETS</b>			
<b>Non-current assets</b>			
<b>Intangible assets</b>			
Capitalized development costs	257,088	161,989	231,618
Patent	-	-	-
<b>Total intangible assets</b>	<b>257,088</b>	<b>161,989</b>	<b>231,618</b>
<b>Property, plant and equipment</b>			
Machinery and installations	26,227	25,642	20,746
Right-of-use assets	5,002	6,366	5,207
Equipment	864	1,166	970
Fixed assets under construction and prepayments	8,590	11,459	15,746
<b>Total Property, plant and equipment</b>	<b>40,683</b>	<b>44,633</b>	<b>42,669</b>
<b>Financial assets</b>			
Financial investments	1	1	1
<b>Total financial assets</b>	<b>1</b>	<b>1</b>	<b>1</b>
<b>Total non-current assets</b>	<b>297,773</b>	<b>206,623</b>	<b>274,288</b>
<b>Current assets</b>			
Current receivables	1,706	2,436	2,667
Prepaid expenses and accrued income	2,435	1,261	2,750
Cash and cash equivalents	292,265	172,740	325,598
<b>Total current assets</b>	<b>296,406</b>	<b>176,438</b>	<b>331,015</b>
<b>TOTAL ASSETS</b>	<b>594,178</b>	<b>383,061</b>	<b>605,303</b>

SEK thousand	31 Mar 2021	31 Mar 2020	31 Dec 2020
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
Share capital	19,068	16,752	18,893
Other contributed capital	713,598	450,576	709,407
Reserves	976	976	976
Retained earnings including profit/loss for the period	-160,601	-104,811	-146,689
<b>Total equity attributable to the Parent Company's shareholders</b>	<b>573,041</b>	<b>363,493</b>	<b>582,587</b>
<b>Non-current liabilities</b>			
Lease liabilities	2,616	4,040	2,898
<b>Total non-current liabilities</b>	<b>2,616</b>	<b>4,040</b>	<b>2,898</b>
<b>Current liabilities</b>			
Trade accounts payable	6,657	4,192	8,438
Lease liabilities	2,078	1,319	1,985
Other current liabilities	1,636	712	768
Accrued expenses and deferred income	8,150	9,304	8,627
<b>Total current liabilities</b>	<b>18,521</b>	<b>15,528</b>	<b>19,818</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>594,178</b>	<b>383,061</b>	<b>605,303</b>

## Consolidated report of changes in equity

SEK thousand	Share capital	Other contributed capital	Reserves	Retained earnings incl profit/loss for the period	Total equity
<b>Opening balance as of January 1, 2020</b>	<b>16,752</b>	<b>450,266</b>	<b>976</b>	<b>-94,279</b>	<b>373,715</b>
Loss of the period	-	-	-	-52,410	-52,410
Other comprehensive income for the period	-	-	-	-	-
<b>Total comprehensive income for the period</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-52,410</b>	<b>-52,410</b>
New share issue	1,861	263,373	-	-	265,234
Transaction costs	-	-16,102	-	-	-16,102
Redemption of warrants / new shares	280	11,560	-	-	11,840
Warrant program	-	310	-	-	310
<b>Closing balance as of December 31, 2020</b>	<b>18,893</b>	<b>709,407</b>	<b>976</b>	<b>-146,689</b>	<b>582,587</b>
<b>Opening balance as of January 1, 2021</b>	<b>18,893</b>	<b>709,407</b>	<b>976</b>	<b>-146,689</b>	<b>582,587</b>
Loss for the period	-	-	-	-13,912	-13,912
Other comprehensive income for the period	-	-	-	-	-
<b>Total comprehensive income for the period</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-13,912</b>	<b>-13,912</b>
Transaction costs	-	-9	-	-	-9
Redemption of warrants / new shares	175	4,200	-	-	4,375
<b>Closing balance as of March 31, 2021</b>	<b>19,068</b>	<b>713,598</b>	<b>976</b>	<b>-160,601</b>	<b>573,041</b>

## Consolidated cash flow statement

SEK thousand	2021	2020	2020
<b>Operating activities</b>			
Operating loss	-14,177	-10,714	-53,457
Non-cash adjustments			
Depreciation	1,955	1,907	7,689
Capital gains	98	-	-113
Dissolved prepaid leasing costs, during the period	-	-473	-1,262
Interest received	569	149	674
Interest paid	-	-7	-8
<b>Cash flow from operating activities before changes in working capital</b>	<b>-11,555</b>	<b>-9,138</b>	<b>-46,477</b>
<b>Changes in working capital</b>			
Change in operating receivables	973	3,066	2,479
Change in operating liabilities	-1,389	-7,418	-3,794
<b>Cash flow from operating activities</b>	<b>-11,971</b>	<b>-13,490</b>	<b>-47,792</b>
<b>Investing activities</b>			
Capitalized development costs	-25,188	-20,193	-88,983
Acquisition of property, plant and equipment	-	-3,725	-4,572
Sales of tangible fixed assets	-	-	383
Prepayments	-	-	-3,656
<b>Cash flow from investing activities</b>	<b>-25,188</b>	<b>-23,918</b>	<b>-96,828</b>
<b>Financing activities</b>			
New share issue	-	-	249,320
Transaction costs	-10	-	-188
Payment of lease liability	-539	-34	-936
Redemption of warrants	4,375	-	11,840
Repurchased warrants	-	-74	-74
Allocated warrants	-	384	384
<b>Cash flow from financing activities</b>	<b>3,826</b>	<b>276</b>	<b>260,345</b>
<b>Cash flow for the period</b>	<b>-33,333</b>	<b>-37,132</b>	<b>115,726</b>
Cash and cash equivalents at the beginning of the period	325,598	209,872	209,872
<b>Cash and cash equivalents at the end of the period</b>	<b>292,265</b>	<b>172,740</b>	<b>325,598</b>

## Parent Company income statement

SEK thousand	Q1		Full year
	2021	2020	2020
Net sales	-	-	-
Other operating income	100	-	1,364
Research and development expenses	-1,598	-1,580	-6,379
Administration and sales expenses	-12,207	-8,576	-47,194
Other operating expenses	-470	-540	-1,172
<b>Operating loss</b>	<b>-14,175</b>	<b>-10,695</b>	<b>-53,381</b>
Finance income	266	186	1,053
Finance costs	-0	-4	-5
<b>Finance net</b>	<b>266</b>	<b>182</b>	<b>1,048</b>
<b>Loss before Income tax</b>	<b>-13,909</b>	<b>-10,513</b>	<b>-52,333</b>
Tax	-	-	-
<b>Loss for the period</b>	<b>-13,909</b>	<b>-10,513</b>	<b>-52,333</b>



## Parent Company balance sheet

SEK thousand	31 Mar 2021	31 Mar 2020	31 Dec 2020
<b>ASSETS</b>			
<b>Non-current assets</b>			
<b>Intangible assets</b>			
Capitalized development costs	256,969	161,886	231,512
Patent	-	-	-
<b>Total intangible assets</b>	<b>256,969</b>	<b>161,886</b>	<b>231,512</b>
<b>Property, plant and equipment</b>			
Machinery and installations	26,227	25,642	20,747
Equipment	864	1,166	970
Fixed assets under construction and prepayments	8,590	11,459	15,746
<b>Total Property, plant and equipment</b>	<b>35,681</b>	<b>38,267</b>	<b>37,463</b>
<b>Financial assets</b>			
Shares in subsidiaries	50	50	50
Financial investments	1	1	1
<b>Total financial assets</b>	<b>51</b>	<b>51</b>	<b>51</b>
<b>Total non-current assets</b>	<b>292,701</b>	<b>200,204</b>	<b>269,026</b>
<b>Current assets</b>			
<b>Current receivables</b>			
Other current receivables	1,706	2,436	2,666
Prepaid expenses and accrued income	2,917	2,365	3,232
<b>Total current receivables</b>	<b>4,622</b>	<b>4,801</b>	<b>5,898</b>
Cash and bank	292,215	172,690	325,548
<b>Total current assets</b>	<b>296,837</b>	<b>177,491</b>	<b>331,446</b>
<b>TOTAL ASSETS</b>	<b>589,539</b>	<b>377,696</b>	<b>600,472</b>

SEK thousand	31 Mar 2021	31 Mar 2020	31 Dec 2020
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<b>Restricted equity</b>			
Share capital	19,068	16,752	18,893
Statutory reserve	976	976	976
Development expenditure reserve	256,969	161,886	231,512
<b>Total restricted equity</b>	<b>277,013</b>	<b>179,614</b>	<b>251,381</b>
<b>Non-restricted equity</b>			
Other contributed capital	713,598	450,576	709,408
Accumulated earnings	-403,606	-256,190	-325,816
Profit/loss for the period	-13,909	-10,513	-52,333
<b>Total non-restricted equity</b>	<b>296,083</b>	<b>183,873</b>	<b>331,259</b>
<b>Total equity</b>	<b>573,095</b>	<b>363,487</b>	<b>582,640</b>
<b>Current liabilities</b>			
Trade accounts payable	6,657	4,192	8,437
Other current liabilities	1,636	712	768
Accrued expenses and deferred income	8,150	9,304	8,627
<b>Total current liabilities</b>	<b>16,444</b>	<b>14,209</b>	<b>17,832</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>589,539</b>	<b>377,696</b>	<b>600,472</b>

## Parent Company cash flow statement

SEK thousand	Q1		Full year
	2021	2020	2020
<b>Operating activities</b>			
<b>Operating loss</b>	<b>-14,175</b>	<b>-10,695</b>	<b>-53,381</b>
Non-cash adjustments			
Depreciation	1,683	1,657	6,694
Capital gains	98	-	-113
Interest received	569	149	674
Interest paid	-	-4	-5
<b>Cash flow from operating activities before changes in working capital</b>	<b>-11,825</b>	<b>-8,893</b>	<b>-46,131</b>
Changes in working capital			
Change in operating receivables	974	3,066	2,311
Change in operating liabilities	-1,390	-7,418	-3,794
<b>Cash flow from operating activities</b>	<b>-12,241</b>	<b>-13,245</b>	<b>-47,614</b>
<b>Investing activities</b>			
Purchase of intangible assets	-25,457	-20,472	-90,098
Acquisition of property, plant and equipment	-	-3,725	-4,571
Sales of tangible fixed assets	-	-	383
Prepayments	-	-	-3,656
<b>Cash flow from investing activities</b>	<b>-25,457</b>	<b>-24,197</b>	<b>-97,942</b>
<b>Financing activities</b>			
New share issue	-	-	249,320
Transaction costs	-10	-	-188
Redemption of warrants	4,375	-	11,840
Repurchased warrants	-	-74	-74
Allocated warrants	-	384	384
<b>Cash flow from financing activities</b>	<b>4,365</b>	<b>310</b>	<b>261,282</b>
<b>Cash flow for the period</b>	<b>-33,333</b>	<b>-37,132</b>	<b>115,726</b>
Cash and cash equivalents at the beginning of the period	325,548	209,822	209,822
<b>Cash and cash equivalents at the end of the period</b>	<b>292,215</b>	<b>172,690</b>	<b>325,548</b>

## Notes

### Note 1. Accounting and measurement policies

The interim report for the Group has been prepared in accordance with IAS 34 Interim Financial Reporting, issued by the International Accounting Standards Board (IASB) and with the applicable provisions in the Swedish Annual Accounts Act. The interim report for the Parent Company has been prepared in accordance with Chapter 9, "Interim Reports", of the Annual Accounts Act. For the Parent Company and the Group, the same accounting policies, and bases for calculation as in the Annual Report for 2020 have been applied.

The changes in IFRS applied as of January 1, 2021 have not had any impact on the financial statements for the first quarter of 2021.

Comparison figures are presented in parentheses and pertain to the year-earlier period.

Xspray Pharma AB (publ) acquired a newly-formed subsidiary, dormant for the time being, at the end of December 2018 in order to prepare the Group structure for potential future structural requirements. No activity has taken place in the subsidiary; all activities are pursued in the Parent Company, Xspray Pharma AB (publ).

#### Definitions of key performance indicators

Earnings per share are calculated as earnings for the period divided by the average number of shares during the period. The debt/equity ratio is equity as a percentage of the balance sheet total.

Research and development costs as a percentage of operating costs comprise primarily expensed research and development expenditures divided by operating costs. Total operating costs consist of operating profit less net sales and other operating income.

The carrying amount of receivables, cash and cash equivalents, trade payables and other liabilities constitute a reasonable approximation of fair value.

### Note 2. Key estimates and assessments

Preparing the financial statements in accordance with IFRS requires management to make assessments and estimates, and to make assumptions that impact the application of the accounting policies and the recognized amounts of assets, liabilities, revenue, and expenses. The real outcome may deviate from these estimates and assumptions. The estimates and assumptions are routinely evaluated. Changes to estimates are recognized in the period the changes are made.

The source of uncertainty in estimations that entail a significant risk for the need to significantly adjust the value of assets or liabilities during the coming financial year is the carrying amount of "Capitalized development expenditures". Determining whether the requirements for capitalization of development expenditures have been met requires both initial and routine assessments. The capitalized expenditures are regularly tested as to whether they could be exposed to a decrease in value. The company holds capitalized intangible assets that have not yet been completed and are impairment tested either yearly or as soon as there is an indication of a potential decrease in value. Impairment testing involves estimating future cash flows attributable for the asset or cash-generating unit that the asset will be attributed to once it is complete. These estimates and assumptions encompass expectations pertaining primarily to the selling price of the products, market penetration, and remaining development, sales and marketing costs as well as the probability that the product will successfully pass through the remaining development stages. The assumptions involve industry- and market-specific data produced by corporate management and reviewed by the Board of Directors.

#### Material risks and uncertainties

Xspray Pharma's operation is associated with both industry-related and company-specific risks. The company develops drug candidates, and there will always be regulatory, market-related, and financial risks in the operation. No material changes have occurred in the risks and uncertainties during the period compared with those the company reported in the Annual Report for 2020.

#### COVID-19

Xspray Pharma continued to adapt its operations to the prevailing circumstances owing to the COVID-19 pandemic. During the preceding fiscal year, there were minor delays to the start of the study with the generic version of Sprycel®. Xspray Pharma sees continued risks in delays associated with COVID-19 that could thereby have a negative effect on its operating activities and studies. Xspray Pharma is taking the measures necessary to reduce the impact of the pandemic on its operation and continually follows the recommendations of the Swedish Public Health Agency.

## Assurance from the Board

The Board of Directors and the CEO declare that this quarterly report provides a true and fair overview of the Group's and Parent Company's business operations, financial position and performance and describes principal risks and uncertainties faced by the company.

Solna, May 6, 2021

Michael Wolff Jensen  
Chairman of the Board

Gunnar Gårdemyr  
Board member

Maris Hartmanis  
Board member

Torbjörn Koivisto  
Board member

Christine Lind  
Board member

Carl-Johan Spak  
Board member

Per Andersson  
CEO

*This report has not been audited.*

## Information

### Glossary

**505(b)(2)** • Application for drug approval in the US for an improved version of an existing licensed or approved drug.

**Amorphous** • An amorphous structure is a chemical term that describes substances whose molecules lack an ordered structure.

**ANDA** • (Abbreviated New Drug Application) Application for generic drug approval in the US for an existing licensed drug or approved drug.

**Bioequivalence** • Term used to describe whether two different drugs are processed in a similar manner by the body and are thereby expected to have a similar equivalent medicinal effect. If it can be confirmed that two drugs being compared are bioequivalent, they can be expected to have the same effect and safety.

**CRO** • Contract Research Organization. A service company active in contract research and service in the development of drugs.

**CMO** • Contract Manufacturing Organization.

**FDA** • Food and Drug Administration. The food and drug agency in the US responsible for foodstuffs, nutritional supplements, drugs, cosmetics, medical equipment, radiation-emitting equipment, and blood products.

**Generic** • Generic drugs are medically exchangeable drugs with the same function, quality, and safety as an original drug.

**GMP** • Good Manufacturing Practice. Rules that describe how the drug industry is to manufacture medicines so that patients can always be sure that they are taking the right product with a high level of quality. The rules govern manufacturing and packaging of drugs, foodstuffs, and nutritional supplements. GMP is a system for ensuring that the products are always produced and checked in accordance with quality norms. The system has been designed to minimize the risks in drug production that cannot be eliminated by testing the final product.

**Pilot study** • An initial sample study conducted on a smaller scale than a full study. A pilot study can be used both to check whether the arrangement of the study is a functional one, and to collect data that can later be used as control values in the full study.

**Pivotal study** • A decision-based clinical trial that will provide data on the effectiveness and safety of the drug for market approval.

**Protein kinase inhibitor (PKI)** • Drugs that block protein kinases. Protein kinase inhibitors work by blocking activity in enzymes that push the development and growth of cancer cells.

This interim report for Xspray Pharma AB (publ) was released after approval by the Board of Directors.

For further information, please contact

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